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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,037	04/08/2004	Mark C. Bates	12212-002-999	9083

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,037	BATES, MARK C.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24 and 26-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-24 and 26-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 26-31, 35-56, 59, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Humes (US 5911704). Humes discloses an implantable device and method comprising the steps of providing an apparatus having an anchor 20 expandable from a delivery configuration to a deployed configuration, and a material 10 adapted to elute a bioactive substance, disposing the anchor in the delivery position, advancing the distal end of a delivery sheath to the delivery site, expanding the anchor to engage the interior wall of a vessel, eluting a bioactive substance, and removing the anchor (Col. 16, line 15 – col. 17, line 20). The drug may be a coagulation factor (Col. 2, lines 20-25). The eluting material may be filaments, which are elongated members adapted for multiple turns. As can be seen in Fig. 6B, the eluting material 10 may comprise two capsules that allow blood to flow therebetween. This is interpreted to meet the claim limitation of eluting material into the blood flowing therethrough.

3. Humes discloses that the anchor 20 comprises a head 26, barbed filaments 22 biased radially outwardly attached at one end to the head. The anchor comprises an interlocking receptacle for receiving an interlocking element 40 of the capsule 10. See Fig. 6A. The reservoir is an osmotic pump (Col. 9, lines 37-42). The reservoir comprises a biocompatible polymeric semi-permeable membrane defining pores of size sufficient to permit diffusion of

preselected drug therethrough over a preselected period of time (Col. 10, lines 16-24, Col. 8, lines 19-22).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Kleshinski (US 6245012). Humes discloses a method of delivering a bioactive substance within a vessel comprising the steps of providing the apparatus described above, expanding the anchor to engage the interior wall, eluting the bioactive substance, and after a predetermined period of time removing the anchor (col. 1, lines 65-68).

6. Humes does not explicitly disclose the steps required for removing the anchor. Kleshinski teaches an anchor for prolonged implantation similar to that of Humes, but further discloses the steps of removing the device. The steps include inserting a catheter to the site within the vessel, engaging the anchor, collapsing the anchor, and removing the apparatus from the vessel (Col. 6, lines 8-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include the specific steps of retrieving the anchor as taught by Kleshinski because Kleshinski teaches a safe way to remove the anchor after it is no longer necessary without releasing any embolic material entrapped within the anchor.

7. Claims 32-33, 57, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong (WO 95/2618). Claims 32, 33 differ from Humes in calling for the eluting material to include a spongy material or a foam. Leong teaches the use of foam to elute drugs after implantation into the body for long term, non-invasive delivery of the drug to a

specific area. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Humes to include a drug eluting foam as taught by Leong to provide long term drug delivery to a specific area within the body.

8. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong. Claim 34 differs from the teachings above in calling for the spongy member to be steel wool. At the time the invention was made, it would have been an obvious matter of design choice to form the drug eluting member of steel wool. Applicant has not disclosed that having steel wool serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Humes and applicant's invention to perform equally well with either a pellet, filaments, foam or steel wool because each are known drug eluting substances. Therefore, it would have been prima facie obvious to modify the device of Humes in view of Leong to obtain the invention as specified in claim 34 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

Response to Arguments

9. Applicant's arguments filed 12/2/08 have been fully considered but they are not persuasive. Applicant argues that Humes teaches away from including an anti-clotting agent. The examiner disagrees. Firstly, Humes specifically discloses that the anchor can be used to elute an anti-coagulant (col. 2, line 24). Secondly, the examiner does not agree with Applicant's assertion that Humes teaches away from the use of an anti-coagulant. Applicant points out that Humes teaches the use of an autologous blood clot. The examiner agrees that this is mentioned in the disclosure, however applicant is mischaracterizing this teaching. Humes clearly implies

that the use of autologous blood clots is *one embodiment* in addition to multiple other embodiments including an embodiment that uses anti-coagulant. The examiner points applicant to column 10, lines 54-60 of Humes' disclosure where it states that, "*Alternatively*, the hollow fibers may be encased within a biocompatible gel, *for example* autologous blood clot…". It is exceedingly clear that this is only one contemplated embodiment that may include an autologous blood clot. Teaching of multiple embodiments should not be viewed as a teaching away from any one disclosed embodiment. Humes clearly discloses the use of an anti-coagulant.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

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